

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

SHANXIANG SHEN

Appln. No.: 10/803246

March 18, 2004

Title:

Filed:

USING COMPLEMENT COMPONENT

C1Q DERIVED MOLECULES AS TRACERS FOR FLUORESCENCE

POLARIZATION ASSAYS

Group Art Unit: TBA

Examiner: TBA

Atty Docket No. 141938.00000

Customer ID 25207

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Respectfully submitted,

POWELL, GOLDSTEIN, FRAZER & MURPHY LLP

Bernard Rhee

Reg. No. 48,816

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The citation of information on the attached Form PTO/SB/08B, Information Disclosure Statement by Applicant, is made pursuant to 37 CFR 1.56 and 1.97. A copy of each of the cited foreign references are enclosed.

The citation of this information does not constitute either an admission of priority or a waiver of any right applicant may have under applicable statutes, Rules of Practice in patent cases, or otherwise.

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			PPLICANT	First Named Inventor	Shanxiang Shen		
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Examiner Initials*	Cite No. ¹	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		ARYA S., et al (1994). "Mapping of amino acid residues in the C mu 3 domain of mouse IgM important in macromolecular assembly and complement-dependent cytolysis." J. Immunol	
		152:(3):1206-12 [Abstract]	
		BUGHIO, Masreen I, et al. (1999). "Use of Recombinant Flagellin Protein as a Tracer Antigen in a Fluorescence Polarization Assay for Diagnosis of Leptospirosis."	
		Clinical and Diagnostic Laboratory Immunology, 6(4): 599-605.	
		BURKE, TJ, et al (2003). "Development and application of fluorescence polarization assays in drug discovery." Comb Chem High Throughut Screen 6(3):183-94 [Abstract]	
	·	CHECOVICH, WJ, et al (1995). "Fluorescence polarizationa new tool for cell and molecular biology." Nature, 375(6528):254-6	
		CHEN, FH, et al (1997). "Domain-switched mouseo lgM/lgG2b hybrids indicate individual roles for C mu 2. C mu 3. and C mu 4 domains in the regulation of the	
		interaction of IgM with complement C1q." J. Immunol 159(7): 3354-63	
		DUNCAN, AR, et al (1988). "The binding site for C1q on IgG." Nature, 332(6166):738-40	
		EGGELING, Christian, et al (2003). "Highly sensitive fluorescence detection technology current available for HTS." Drug Discovery Today 8(14):632-641.	

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Sheet	2	of	4	Attorney Docket Number	141938.00000	

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		EREMIN, SA, et al. (2003). "Fluorescence polarization immunoassays for pesticides." Comb Chem High Throughput Screen 6(3):257-66 [Abstract]	
		GOMEZ-Hens, A, et al. (2003). "Stopped-flow fluorescence polarization immunoassay." Comb Chem High Throughput Screen 6(3):177-82	
		HARAYAMA, S (1998). "Artificial evolution by DNA shuffling." Tibtech 16:76-82	
		HONG, JY, et al (2002). "Development of One-Step Fluorescence Polarization immunoassay for Progesterone." Biol. Pharm. Bull. 25(10):1258-1262	
		JAMESON, DM, et al. (2003). "Fluorescence Polarization: Past, Present and Future." Combinatorial Chemistry & High Throughput Screening 6:167-176	
		JOHNSON, DK (2003). "Fluorescence polarization immunoassays for metal ions." Comb. Chem High Throughput Screen 6(3):245-55	
		JOLLEY, ME, et al (2003). "The use of flouroescence polarization assays for the detection of infectious diseases." Comb. Chem High Throughput Screen, 6(3):235-44 [Abstract]	
		KISHORE, U, et al. (2003). "Modular Organization of the Carboxyl-Terminal, Globular Head Region of Human C1q A, B, and C Chains." Journal of Immunology, 171:812-820.	
		KISHORE, U, et al. (2002). "Recent Progress in the Understanding of the Structure-Function Relationships of the Globular Head Regions of C1q." Immunobiology, 205:355-364	
		KISHORE, U, et al (1998). "Functional characterization of a recombinant form of the C-terminal globular head region of the B-chain of human serum complement protein, C1q."	
		Biochem J 333.27-32	——

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		KISHORE, Uday, et al. (2001). A recombinant homotrimer, composed of the helical neck region of human sufractant protein D and C1q B chain globular domain, is an inhibitor	
* * f		of the classical complement pathway. J. Immunology, 166:559-565.	
		KOJOUHAROVA, MS, et al. (2003). "Localization of ligand-binding sites on human C1q globular head region using recombinant globular head fragments and single chain antibodies	11
		Biochimica et Biophysica Acta, 1652:64-74.	
		KOLKMAN, JA, et al. (2001). "Directed evolution of proteins by exon shuffling." Nature, 10:423-428	
		LIN, M, et al. (1997). "Binding of the Brucella abortus Lipopolysaccharide O-chain fragment to a monoclonal antibody." J. Biological Chem. 272(5):2821-2827	
		LIN, M, et al. (1996). "Modification of the Mycobacterium bovix extracellular protein MPB70 with fluorescein for rapid detection of specific serum antibodies by fluorescence	
		polarization." Clinical and Diagnostic Laboratorý Immunology, 3(4):438-443.	
		MENZEL, JE, et al (1991). "A method to differentiate between anti-C1q antibodies and C1q-binding immune complexes using collagenase-digested solid phase C1q."	
		Journal of immunological Methods, 138:1654-171.	

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		MORGAN, A, et al. (1995). "The N-terminal end of the CH2 domain of chimeric human IgG anti-HLA-DR is necessary for C1q, Fc gamma RI and Fc gamma RIII binding." Immunology,	l
		86(2):319-24	
		MORRISON, KL, et al. (2001). "Combinatorial alanine-scanning." Curr Opin Chem biol 5(3):302-307	
		PAINTER, RH (1984). "The C1q receptor site on human immunoglobulin G." Can J. Biochem Cell Biol. 62(6):418-25	
		REID, KB (1989). "Chemistry and molecular genetics of C1q." Behring Inst. Mitt (84):8-19	
		TRINDER, PK, et al (1993). "Functional domains of the human C1q A-chain." Behring Inst Mitt (93):180-8	
		WATSON, A, et al (2003). "Lighting up cells with quantum dots." BioTechniques, 34(2):296-303	
		WEIDMANN, GL, et al. (1993). "Establishment of reference ranges for thyrotropin, triiodothyronine, thyroxine and free thyroxine in neonates, infants, children and adolescents."	
-	· 	Eur J. Clin Chem Clin Biochem 31(5):277-8	
		WONG, SH (1987). "Methodologies for antidepressant monitoring." Clin Lab Med 7(2):415-33	

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